CHAPTER 5
RISK

CHAPTER CONTENTS

This chapter integrates the hazard, dose-response, and exposure assessments for several major commercial clothes cleaning processes into a risk assessment for each of the cleaning processes and characterizes the risks as to key issues, major assumptions, and uncertainties. Section 5.1 provides definitions of terms common to risk assessment and descriptions of methodologies. Section 5.2 presents estimates of potential risks to workers, co-located residents (i.e., residents in buildings with drycleaning facilities), and the general population, as well as environmental risks from perchloroethylene (PCE). Section 5.3 estimates potential risks from drycleaning operations using hydrocarbon (HC) technology. Section 5.4 evaluates the risks associated with machine wetcleaning.

5.1 RISK CHARACTERIZATION—INTRODUCTION

5.1.1 Scope of the CTSA Risk Assessments

This chapter integrates the hazard, dose/response, and exposure assessments for several commercial clothes cleaning technologies into a risk assessment for each of the cleaning processes and characterizes the risks as to key issues, major assumptions, and uncertainties. A summary and characterization of risk are given for each of the following cleaning processes: drycleaning with PCE; drycleaning with HC; and machine wetcleaning. When information is available, risks for exposures to different machinery within processes are also addressed.

The risk assessments were conducted at a "screening level" of review, using readily available information and standard analyses for completion. The risk assessments and characterizations should give an idea of the risks to human health and the environment associated with each of the processes and offer a basis for comparison. However, since the extent and type of hazard and exposure data and uncertainties associated with each process differ widely, the risk comparisons among processes will give only a general, "ballpark" type of comparison. Information is developed with the intent of identifying the types of potential health and environmental risks associated with various clothes cleaning technologies to allow clothes cleaners to better understand the potential implications of technology choices. The information is organized to provide general background on terminology and elements of risk assessment and to present general risk characterizations for individual technologies.

5.1.2 Background Information on Human Risk Assessment Methodology

This section presents general information to increase understanding of the risk assessment process used in this CTSA document. The principles of the risk assessment process are defined, and general methodologies used in classifying potential human health risk are explained. (A description of ecological risk methodology is given in Appendix B.)

Definitions—Risk Assessment

A risk assessment is an interactive process that generally includes the following components of analysis:

(1) Hazard Assessment & Characterization, the process of determining whether or not exposure to a chemical can cause adverse health effects in humans. It includes explanation of the evidence of toxicity and describes major points of interpretation and assumptions. In addition, it explains strengths and weaknesses of the data and analyses, as well as major uncertainties.

(2) Dose-response Assessment & Characterization, the process of defining the relationship between the dose of a chemical received and the incidence and severity of adverse health effects in the exposed population. From a quantitative dose-response relationship, toxicity values are derived and used in the risk characterization step to estimate the likelihood of adverse effects occurring in humans at different anticipated exposure levels. It includes explanation of key scientific issues and assumptions, strengths and weaknesses of the data and analyses, and major uncertainties.

(3) Exposure Assessment & Characterization, which identifies populations exposed to a chemical, describes their composition and size, and presents the types, magnitudes, frequencies, and durations of exposure to the chemical. It includes discussion of key issues, description of methods used, and strengths and weaknesses of the data and analyses. Major uncertainties are also discussed.

(4) Risk Characterization, which integrates hazard, exposure, and dose-response information into qualitative and/or quantitative expressions of risk. A risk characterization includes a description of the major assumptions and key issues, scientific judgments, strengths and weaknesses of data and analyses, and the uncertainties embodied in the assessment.

Methods—Expressions of Human Health Risk

The manner in which estimates of hazard and risk are expressed depends on the human health endpoint of concern and the types of data upon which the assessment is based. Overall, cancer risks are most often expressed as the probability of an individual developing cancer over a lifetime of exposure to the chemical in question. Risk estimates for adverse effects other than cancer are not expressed as probabilities of occurrence; instead, a concentration or dose associated with the presence or absence of a specific toxic endpoint of concern is compared to an estimated dose or exposure level for the population considered. This comparison is expressed as a ratio, which is an indicator of the margin by which the population's exposures differ from (exceed or not) levels where individuals are expected to be free of adverse/deleterious effects. A key distinction between cancer and other toxicologic effects is that *most* carcinogens are generally assumed to have no dose threshold; i.e., no dose or exposure level can be presumed to be without some risk. Other toxicologic effects are generally assumed to have a dose threshold; i.e., a dose or exposure level below which a significant adverse effect is not expected.

Sometimes understanding a process requires characterization of a mixture of chemicals, rather than a single one. Under ideal circumstances, information would be available for the mixture or formulation.

More typically, information is available on at least some ingredients (components). Often, certain components are exchangeable, with selection based on their function in the process, but with exposure and toxicity properties unique to the selection. In Section 5.4, information on examples of these selections will be provided for the machine wetcleaning process. Quantitative assessment of mixtures using their components often relies on the assumption that the components produce their toxicities independently; information on ways one or more components may modify others is incorporated qualitatively. Mixtures with just a few ingredients may be characterized more readily than mixtures with many dissimilar ingredients.

Quantitative Expressions of Risk - Not all substances evaluated for the CTSA have been reviewed previously or have sufficient data available for quantitative expressions of risk. Only PCE has such information for cancer. Only PCE and some hydrocarbon solvents have such information for quantitative expression of other risks.

Cancer Risk Assessment

USEPA employs a "weight-of-evidence" approach to determine the likelihood that a chemical is a human carcinogen. The USEPA's Cancer Risk Assessment Guidelines (USEPA, 1986) and in particular, its proposed cancer guidelines (USEPA, 1996), emphasize the use of all pertinent information, not just tumor findings in animals or humans, in making a decision about a chemical agent's carcinogenic potential. This recognizes that information about mode of action of carcinogenic agents at the cellular and sub-cellular levels, as well as toxicokinetic and metabolic process information, should play an important role in evaluating carcinogenic toxicity. According to the 1986 guidelines, EPA describes a chemical's carcinogenic potential by placing it in one of five weight-of-evidence categories [from Group A (human carcinogen) to Group E (evidence of noncarcinogenicity for humans)] and providing a "basis" statement. The 1996 proposed guidelines recommend major categories (and subcategories) that would be more informative by requiring a brief narrative of information on all the evidence available to be included with each category. In extracting information for this chapter, the CTSA, as a screening level assessment, has aimed to incorporate the spirit of the narrative approach rather than categories per se.

Cancer Risk Indices -Where the available data are sufficient for dose-response assessment, EPA has developed an estimate of the chemical's carcinogenic potency. An oral "slope factor" expresses carcinogenic potency in terms of the estimated incremental upper bound excess lifetime risk per mg/kg average daily dose ingested. "Unit risk" is a similar measure of potency for air or drinking water concentrations and is expressed as risk per $\mu g/m^3$ in air or as risk per µg/L in water for continuous lifetime exposures. Underlying the unit risk concept is the assumption that the relationship between dose and level of excess risk is linear; that is, for a given incremental change in dose, there is a proportional change in estimated risk level. This is referred to as the "linear at low dose" approach throughout this assessment. The unit risk or slope factor is regarded as an upper bound on the incremental lifetime excess cancer risk because it is derived in a way intended to account for experimental variability and extrapolation uncertainties. The lower bound on lifetime excess cancer risk is always recognized to be as low as zero. As described in Appendix D, where possible the experimental data can be used to estimate a magnitude of excess risk, but can only suggest how well the upper bound reflects true excess.

Cancer excess risk is calculated by multiplying the estimated dose or exposure level by the appropriate measure of carcinogenic potency. For example, an individual with a lifetime average daily

dose of 0.3 mg/kg of a carcinogen with a slope factor of 0.02 per mg/kg/day would experience a lifetime excess cancer risk of 0.006 [6 X 10^{-3} or a risk of 6 in 1000] from exposure to that chemical. These risks are identified as incremental over background; i.e., beyond those ordinarily sustained by the general population with no particular exposure to the chemical. In general, risks from exposures to more than one carcinogen are assumed to be additive, unless information points toward a different interpretation; that is, when available, component quantitative estimates may be summed to obtain the mixture's estimate.

Risk Assessments for Human Health Toxicities Other Than Cancer

Because adverse effects other than cancer and gene mutations are generally assumed to have a dose or exposure threshold, a different approach is widely used to evaluate potential risk for these non-cancer effects, such as liver toxicity, neurotoxicity, and kidney toxicity. EPA uses the Reference Dose (RfD) or Reference Concentration (RfC) approach to evaluate such chronic effects. The RfD or RfC is defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime" and is expressed as a mg/kg/day dose or mg/m^3. The RfD or RfC is usually based on the most sensitive known effect; i.e., the effect that occurs at the lowest dose. The basic approach for deriving an RfD or RfC involves determining a "no-observed-adverse-effect level (NOAEL)" or "lowest-observed-adverse-effect level (LOAEL)" from an appropriate animal study or human epidemiologic study, and applying various uncertainty and modifying factors to arrive at the RfD/RfC. Each factor represents a specific area of uncertainty. For example, an RfD based on a NOAEL from a long-term animal study might incorporate a factor of 10 to account for the uncertainty in extrapolating from the test species to humans, and another factor of 10 to account for the variation in sensitivity within the human population. An RfD based on a LOAEL typically contains yet another factor of 10 to account for the extrapolation from LOAEL to NOAEL. An additional modifying factor (between 1 and 10) is sometimes applied to account for uncertainties in data quality.

To characterize potential risk of adverse health effects other than cancer, a "Hazard Quotient" method is calculated. A "Hazard Quotient" is the ratio of the estimated chronic dose/exposure level to the RfD/C. Hazard Quotient values below unity imply that adverse effects are very unlikely. The more the Hazard Quotient exceeds unity, the greater the level of concern. It is important, however, to remember that the Hazard Quotient is not a probabilistic statement of risk. A quotient of 0.001 does not mean that there is a one-in-a-thousand chance of the effect occurring, it just means that the event is "very unlikely to occur." Furthermore, it is important to remember that the level of concern does not necessarily increase in a linear manner as the quotient approaches or exceeds unity, because the RfD/C does not provide any information about the shape of the dose-response curve.

In general, the index of a mixture is derived by summing the Hazard Quotients for each of its components. Risks from exposures to more than one chemical are considered individually for each type of toxicity and organ affected.

An expression of risk that can be used with non-cancer toxicity evaluations when an RfD/C is not available is a ratio of the expected exposure to a NOAEL or LOAEL from an animal or human study (preferably a chronic study). This alternate approach is meant to determine the proximity of the exposures from the various scenarios for humans to the animal or human experimental range. As with the Hazard

Quotient, it is important to remember that this ratio is not a probabilistic statement of risk. Further, if the ratio is based on a LOAEL, even a ratio of unity may not indicate low concern.

Interpreting the Risk Results: Risk Estimates in the Tables and Text

The tables present Risk Indices for cancer risk and Hazard Quotients for non-cancer risks. The Risk Indices are an estimate of individual cancer risk above background level (and are expressed, for example, as 1×10^{-2} or a 1 in 100 risk). The Hazard Quotients are ratios of the expected human exposure to RfC or RfD values.[1] Hazard Quotients above 1 (which indicate exposure values greater than the RfC or RfD) are considered less likely to be free of deleterious effects.

In general, the index of a mixture is derived by summing the component Hazard Quotients. Risks from exposures to more than one chemical are considered individually for each type of toxicity and organ affected. When the component RfD/Cs reflect different toxicities or target organs, an index analogous to the Hazard Quotient can be formed, using a target organ toxicity dose based on NOAELs or modeled levels (Mumtaz et al., 1997). A sum based solely on all the component RfD/Cs is believed to be high for specific organ toxicities. Thus, there may be several quantitative indices for a particular formulation. When each index is less than 1, and all relevant effects have been considered and are believed to be independent, it may be more appropriate to consider the formulation free of significant toxicity overall than when the indices are less than 1 but important information is missing (such information might indicate that the ingredients interact). Such an analysis is usually not conducted when some components do not have RfD/Cs.

Exhibit 5-1 summarizes the different exposure scenarios evaluated by the CTSA in Chapter 4, which are considered for discussion of risk in this chapter.

[1]Note: the provisional occupational RfC used in the Hazard Quotients dealing with occupational exposures of PCE differs from the provisional RfC used for all other PCE exposure scenarios, and any RfC in non-PCE exposure scenarios. This is due to the use of an uncertainty factor of 10 only, in the derivation of the provisional RfC for the PCE occupational scenario (see Appendix D).

Exhibit 5-1. Exposure Scenarios Evaluated for Human Health Effects

Exposed Population	Exposure Routes and Pathways					
	Inhalation Exposure		Ingestion Exposure		Dermal Exposure	
	Residence	Workplace	Nursing (Infants)	Drinking Water	Bathing	Workplace
Perchloroethylene						
Workers		✓				✓
Co-located Adults	✓			✓	✓	
Co-located Elderly, Infants and Children	✓		✓			
General Population - Adults	✓			✓	✓	
General Population - Elderly, Infants and Children	✓					
Hydrocarbons						
Workers		✓				✓
General Population - Adults	✓			✓		
General Population - Elderly, Infants and Children	✓			✓		
Machine Wetcleaning Chemicals						
Workers						✓

✓ Indicates that this pathway-population combination is considered in the CTSA

5.2 DRYCLEANING USING PERCHLOROETHYLENE (PCE)

5.2.1 Human Health

Human data indicate that PCE is absorbed into the body via inhalation, from the gastrointestinal tract following ingestion, and through the skin. There is human evidence indicating that PCE can cause neurotoxicity and kidney effects, and animal data show that PCE can cause other effects, including cancer, developmental toxicity, and liver effects. Toxicity comparison values for use in risk assessment are shown in Exhibit 5-2.

Exhibit 5-2. Toxicity Comparison Values for PCE Risk Assessment

Effect	Toxicity Value	Toxicity Value Type	Basis for Toxicity Value: Species/ Duration/Route
Cancer[a]	0.00071 per mg/m^3	Unit risk	Mouse and rat 2 year inhalation bioassay+ inhalation metabolism information[c]
Cancer[a]	270 mg/m^3	ED_{10}	Mouse and rat 2 year inhalation bioassay + inhalation metabolism information[c]
Cancer	.051 per mg/kg/day	Oral Slope factor	Mouse 2 year gavage bioassay + gavage metabolism information[d]
Critical effects (i.e., most sensitive effects)	0.01 mg/kg/day	RfD	Mouse 6 week gavage study (liver)[e]
	0.17 mg/m^3	"RfC_{PCE}"[b]	"RfC": Human cross-sectional occupational study (renal)[f]

[a] Derivation of the unit risk and ED_{10} values are described in Appendix D. Unit risk is 7.1×10^{-7} per $\mu g/m^3$, which is converted to mg/m^3 by multiplying as follows:
7.1×10^{-7} per $\mu g/m^3 \times 1{,}000\ \mu g/mg = 7.1 \times 10^{-4}$ per mg/m^3, or 0.00071 per mg/m^3.
[b] RfC_{PCE} is a provisional RfC developed specifically for use in this document. Unlike the other RfCs and RfDs in this document, it has not undergone formal USEPA review and approval. Details on the derivation of the provisional RfC can be found in Appendix D.
[c] NTP (1986).
[d] NCI (1977).
[e] ATSDR (1993), Buben and O'Flaherty (1985), IRIS (1997).
[f] Franchini et al. (1983).

5.2.2 Human Health Risks

Risk—General

In this section, the hazards and dose-response relationships of PCE are integrated with individual exposure scenarios to address potential risks of PCE to humans and the environment. These risks are presented in tables and discussed with each exposure scenario.

For PCE, in addition to the linear at low dose approach described in Section 5.1.2, a second approach is used. As discussed in Appendix D, questions remain as to the appropriate use of a linear model to represent relative cancer risks at low exposures to PCE. Therefore, a measure of relative risk, suggested by USEPA (1996), is also used in this assessment. This is called the Margin of Exposure (MOE) nonprojection approach (see Appendix D). The intent of the nonprojection approach is to determine the proximity of the exposures from the various scenarios for humans to the animal experimental range, roughly represented by the ED_{10}, the **dose** (in human equivalents) associated with an estimated **excess** tumor response in 10% of an experimental group. [Note: the acronym ED_{10} has no relation to the acronym ED (exposure duration) used extensively in Chapter 4.] The comparison is evaluated by the ratio of the ED_{10} to expected exposure. The ratio is evaluated in this direction because it is hoped that exposures will be far from the range where an excess 10% of the population would show cancer, and a large ratio will be easier to evaluate. Again, the aim of using any approach is to highlight those PCE exposure scenarios that may warrant the most attention for possible risk reduction.

Quantitative Expressions of Risk—Cancer Risk Indices

Relative indices of cancer risk to exposed population groups are presented for various exposure scenarios. These indices are derived as follows:

- For each exposure scenario, an estimated inhalation exposure of PCE in milligrams per cubic meter (mg/m^3) is averaged over a lifetime to generate a Lifetime Average Daily Concentration (LADC). [Footnote "a" in Exhibit 5-3 gives an example of such a calculation.]

- The calculated LADCs are multiplied by the unit risk of 0.00071 per mg/m^3 (unit risk is defined in section 5.1.2) to give linearly-based upper bound lifetime excess risks, called "linear risk indices" hereafter; or divided into the ED_{10} of 270 mg/m^3 to give MOE indices.

In comparing scenarios in these exhibits, one linear risk index value is of greater concern than another if it is **larger,** e.g., 2×10^{-3} (0.002) is of more concern than 5×10^{-4} (0.0005).

When considering oral exposure scenarios, the Lifetime Average Daily Dose (LADD) is used (see footnote "a," Exhibit 5-7, for sample calculation) instead of the LADC. The LADD is multiplied by 0.051 per mg/kg/day, the slope factor used for oral exposure to PCE (USEPA, 1985), to give a linear risk index value.

The comparison toxicity values and cancer comparison values for use in risk assessment are shown in Exhibit 5-2. These values are compared with predicted (modeled) human exposures to determine

whether any of the PCE exposure scenarios poses a concern for cancer or non-cancer effects to the people exposed.

Routes of Exposure

Inhalation

Human exposure to PCE occurs in three ways; inhalation, oral, and dermal. By far, inhalation exposure is the most significant route of exposure. PCE is well absorbed from the lung following inhalation exposure. For purposes of this risk assessment, inhalation and oral doses are assumed to be absorbed 100% into the body.

Oral

Oral exposure to PCE may occur from ingestion of contaminated drinking water or foods (not evaluated here), or from ingestion of breast milk from PCE-exposed mothers. PCE is well absorbed from the gastrointestinal tract following ingestion. Metabolism of absorbed PCE is expected to be low, roughly 20% (USEPA 1985).

Dermal

Dermal absorption is possible from activities that require contact with PCE, as might occur in occupational settings. Dermal absorption can occur not only from direct contact with the liquid, but also from contact with the vapor in the air. Dermal absorption from the liquid state can be modeled. Dermal absorption from vapor may be estimated as approximately equal to the amount absorbed by the inhalation route at low exposure levels (e.g., 58 ppm); or it may be as low as 1% of the amount absorbed by the inhalation route at higher doses (e.g., 600 ppm) [McDougal et al., 1990; Riikimaki and Pfaffli, 1978; as cited in Keifer 1998. Refer to Appendix C.]

5.2.3 Occupational Risks—Drycleaning Workers

Risk from PCE Inhalation

The number of workers exposed to PCE in drycleaning facilities is estimated to be between 119,000 and 278,000 (Chapter 4). The most significant route of exposure for workers is expected to be from inhalation of PCE, although they may also experience dermal exposure. Several data sets provided maximum exposure concentrations (ECs) for PCE inhalation by drycleaning workers. Average ECs were also provided in some of these data sets, and calculated from others. The data are discussed extensively in Chapter 4 and illustrate variations in worker inhalation exposures due to factors such as machine type and controls, number of machines, job category, and date of PCE exposure. In general, increased exposures to PCE would result in an increase in health risk. Therefore, indications (as summarized in Chapter 4) that there are higher PCE exposures for operators/cleaners compared with other job categories; and for workers exposed to transfer machines compared with dry-to-dry machines; and for workers exposed to more than one machine, are also indications for increased health risks to these workers. On the other hand, indications (Chapter 4) that there has been a general decrease in drycleaning exposures to PCE over the past decade, and that new,“fifth generation” machines result in lower worker exposures, indicate health

risks can be decreased for workers in those situations. The extent of such trends is variable and is not estimated for this CTSA.

Two studies That include the largest numbers of measurements (OCIS, 1994, 1998; and IFI, 1990) are used for the purpose of assessing workers' risk. The data from these two sources are presented in Exhibits 5-3 and 5-4 and discussed below.

Exhibit 5-3. Occupational Health Risks Via Inhalation to Workers Based on Post-1990 OSHA Monitoring Data for PCE Drycleaning

Job Description #1	Geometric Mean EC[e] (mg/m^3) (+) GSD #2	Maximum EC (mg/m^3) #3	LADC[a] (mg/m^3) #4	Cancer Risk Index[g] (Unit risk[b] x LADC) #5	Non-Cancer Hazard Quotient[f] LADC / Prov. Occ. RfC #6
1990 to1993					
All Jobs [N=386]	69 ± 62	5,000	14	1×10^{-2}	8.2
Cleaner [N=157]	80 ± 76	5,000	16	$>1 \times 10^{-2}$ [d]	9.5
Spotter [N=37]	53 ± 77	1,100	10	7×10^{-3}	5.8
Manager [N=43]	250 ± 31	4,300	49	$>1 \times 10^{-2}$ [d]	1.7
Presser [N=41]	37 ± 39	470	7	5×10^{-3}	4.1
1997					
All Jobs [N=40]	42 ± 51	2,500	8	6×10^{-3}	4.5

[a] LADC = Exp. x $\frac{10\ m^3}{20\ m^3}$ x $\frac{250\ days}{365\ days}$ x $\frac{40\ years}{70\ years}$

where Exp. = Mean exposure concentration (occupational exposure) in mg/m^3
10 m^3 = Volume of air inhaled during an 8 hr workday
20 m^3 = Volume of air inhaled in 24 hours
250 days = Days worked per year for the average worker (this is not the same as the number of days the facility is in operation)
365 days = Days per year
40 years= Years worked in a lifetime
70 years = Average lifetime

[b] The Unit Risk is 0.00000071 per $\mu g/m^3$ x 1,000 $\mu g/mg$ = 0.00071 per mg/m^3.
[c] ED_{10} = 270 mg/m^3
[d] The LADC exceeds the limit for use of the unit risk
(Note: when LADC exposure levels are >14 mg/m^3, the unit risk should not be used ; therefore, the risk indices are listed as $>1 \times 10^{-2}$, see Appendix D).
[e] The geometric means are used because these have been used historically with occupational data. A geometric mean gives a feel for the median or 50th percentile of values. GSD= Geometric Standard Deviation.
[f] Provisional occupational RfC = 1.7 mg/m^3 TWA (see Appendix D) Sample HQ: "All Jobs" : HQ = 14 mg/m^3/ 1.7 mg/m^3 = 8.2.
[g] Cancer risk index = upper bound lifetime excess cancer risk.

Exhibit 5-3 presents data on PCE inhalation collected by OSHA during compliance inspections or complaint investigations for 1990–93 and for 1997 (OCIS 1994, 1998). Column #1 lists job descriptions and the number of persons sampled from each job category. In 1997, information for "all jobs" is presented. The OSHA data do not give the types nor numbers of drycleaning machines used.

Column #2 presents average PCE exposure concentrations in mg/m^3 presented as geometric means, and Column #3 gives maximum exposure concentrations in mg/m^3. As indicated by the large geometric standard deviations, there is wide variation around the mean exposures. In addition, there are some occasions when exposures can be quite high, as shown in Column #3. Column #4, LADC (Lifetime Average Daily Concentration), assumes that a worker spends 40 years in the drycleaning industry at mean exposure concentrations.

Column #5 gives an indication of upper bound lifetime excess cancer risk for each job type, given average exposures. It can be inferred from the Risk Index that the estimated excess risk for cancer is likely high for workers in all job categories (between 1 in 100 and 6 in 1000). Also, it can be seen from the table that the PCE lifetime average daily concentrations (LADC) for workers in most job categories are only about 20-fold lower than the ED_{10} dose of 270 mg/m^3 [i.e., the dose in human equivalents at which 10% of the animal study population showed excess tumors; see Exhibit 5-2]. Using a margin of exposure (MOE) nonprojection ratio approach as an alternate way of looking at cancer risk shows that there is not much margin between the ED_{10} and the workers' average concentration levels. (When MOEs are calculated for the average exposure levels of the six worker job categories, they range from 6 to 39). MOEs for workers at the maximum range from 0.02 to 0.6, indicating that there is virtually no margin of exposure from the projected 10% effect level to the workers' exposure for each worker job category.

An assessment of non-cancer risk is given in Column #6. This column lists hazard quotients (HQs) for the six worker job categories for lifetime average daily exposures. All the HQs were greater than 1, indicating a concern for non-cancer toxicity risks to these workers. Also, since there is some indication from animal studies that PCE can cause developmental toxicity at high exposures, there would be concern for developmental toxicity at the maximum PCE levels above 2,000 mg/m^3 (see Appendix C for discussion of developmental toxicity).

Exhibit 5-4 (derived from Exhibit 4-5) uses data from a study conducted by the International Fabricare Institute (IFI, 1990). It shows the mean inhalation exposures and subsequent health risks to workers described as "operators" and as "non-operators." It also considers PCE exposures from "dry-to-dry" and "transfer" machines separately. Exposures from transfer machines are greater for both job categories.

Column #1 lists both job descriptions—"operators" and "non-operators"—as well as two types of machines, "transfer" and "dry-to-dry," to which the workers were exposed. Column #2 gives the average exposure concentrations in mg/m^3 as arithmetic means. These data show that "operators" have greater average PCE exposures than "non-operators," regardless of machine type. It also shows that workers in facilities with transfer machines had greater average exposures than workers in facilities with dry-to-dry machines. Column #3, "Risk Index," gives an indication of upper bound lifetime excess cancer risk for operators and non-operators, each group exposed to PCE from transfer machines, or from dry-to-dry machines. It can be inferred that the estimated excess risk for cancer is projected to be high (1 in 100 or greater) for both job categories.

Exhibit 5-4. Occupational Health Risks to Drycleaning Workers From PCE Inhalation - by Job Title and Machine Type

Job Description/ Machine Type #1	Arithmetic Mean Exp.[a] (mg/m^3) #2	LADC[b] (mg/m^3) #3	Cancer Risk Index[c] (Unit risk x LADC) #4	Non- Cancer Hazard Quotient[d] LADC/Prov. Occ. RfC #5
Operators				
Dry-to-dry (N=1,301)	115	23	$>1 \times 10^{-2}$	13.5
Transfer (N=1,027)	328	64	$>1 \times 10^{-2}$	37.6
Non-operators				
Dry-to-dry (N=497)	79	15	1×10^{-2}	8.8
Transfer (N=508)	179	35	$>1 \times 10^{-2}$	20.6

[a] Arithmetic means used because only arithmetic means were reported in published study.
[b] LADC calculated as for Exhibit 5-3. (Note: when LADC exposure levels are >14 mg/m^3, the unit risk should not be used; therefore, the risk indices are listed as $>1 \times 10^{-2}$. See Appendix D).
[c] Cancer risk index = upper bound excess lifetime cancer risk.
[d] Provisional occupational RfC = 1.7 mg/m^3 TWA (see Appendix D). Sample HQ: "Operators Dry-to-dry": HQ = 23 mg/m^3/1. 7 mg/m^3 = 13.5.

In addition, if we use a margin of exposure (MOE) nonprojection ratio approach to compare the lifetime average daily concentrations (LADC) of PCE for workers in both job categories with the ED_{10} of 270 mg/m^3, we find that the workers' exposures are about 10-fold lower than the ED_{10}. When MOEs are calculated for the four scenarios listed in Exhibit 5-4 they range from 4 to 18.

An assessment of non-cancer risk, using the hazard quotient (HQ) approach, is given in Column #5. All of the HQs are greater than one indicating a potential for non-cancer toxicity to these workers.

Risk From Dermal Exposures

Drycleaning workers are not only exposed to PCE through inhaling the vapor, but also through dermal contact. The two studies cited in Exhibits 5-3 and 5-4 give an indication of exposures and risks due to inhalation. There are no comparable data, however, to assess worker dermal exposures to PCE, and therefore, only a qualitative statement of risk can be made. Dermal exposures can occur through exposures to liquid PCE, such as when handling wet clothes, or when the skin is exposed to PCE vapor present in the workplace. Chapter 4 used a model to estimate possible dermal exposures to liquid PCE. It assumed 1,300 cm^2 as the surface area of two hands, and 24 minutes total duration of contact with the liquid. Using this information, and limited information on absorption rates (Riihimaki et al., 1978; McDougal et al., 1990; Bogen et al., 1992; in Keifer, 1998), a rough estimate can be made of PCE absorbed dermally by workers.[2]

[2] 0.243 mg/cm^2/hour x 1,300 cm^2 x 24 minutes/60 minutes/day = 126 mg/day divided by 70 kg = 1.8 mg/kg/day PCE absorbed dermally from liquid contact.

Absorption of PCE vapor through the skin is another source of PCE exposure to workers in drycleaning facilities. There are some very limited data indicating that PCE vapor can be absorbed through the skin (Riihimaki et al., 1978; McDougal et al., 1990; Bogen et al., 1992; in Keifer, 1998). These data indicate that absorption of PCE vapor through the skin may be equal to the amount of PCE absorbed via inhalation in situations where the PCE vapor levels are in the range of 58 ppm (400 mg/m^3). In situations where PCE vapor levels are 10-fold higher, (i.e., in the range of 600 ppm [4,000 mg/m^3]), the amount absorbed via the skin would be about 1% of that absorbed via inhalation.

It is assumed that dermal and inhalation exposures of PCE to workers would be additive and dermal exposure could be an important route of entry of PCE into the body.

Combined Risks from Inhalation and Dermal Routes

The health risks to drycleaning workers from PCE depend on PCE entering the body through two major routes—inhalation and through the skin. (Oral, hand-to-mouth exposure is not considered a major route, but would also be added to the total risk). Dermal exposures can be from direct contact with liquid PCE or PCE vapor. The risks from dermal exposures would be added to the risks indicated for inhalation in Exhibits 5-3 and 5-4.

Risk Conclusions—Occupational Exposures

There is a reasonable basis to conclude that there can be a health risk for cancer and non-cancer effects to workers from the relatively high PCE exposures observed on average in the drycleaning industry. This conclusion is based on monitored worker inhalation exposure data from several sources, from information about the circumstances of dermal exposures in the workplace and the absorption potential of PCE through the skin, combined with evidence from animal studies indicating that PCE can cause cancer and non-cancer toxicity in laboratory rodents. The cancer risk analysis used both the unit risk approach and the MOE nonprojection ratio approach. The unit risk approach is tied to an upper bound lifetime excess cancer risk estimate and there is the possibility that the lower bound is as low as zero.

The International Agency for Research on Cancer (IARC) recently reviewed the human and animal cancer data on PCE (IARC, 1995). IARC concluded that PCE is a probable human carcinogen.

Although a provisional RfC was developed for potential non-cancer effects of PCE, to which lifetime exposures would be compared, occupational exposures are properly compared to shorter-term exposures. Because the provisional RfC, based on an occupational level, encompassed evaluation of all types of possible effects, it may be expected that exposures in the workplace at monitored levels offer little or no margin from deleterious effects of some kind. Also, there is an indication that there may be developmental toxicity effects, since one of the studies in the database indicated developmental effects at 300 ppm (2,000 mg/m^3) (Schwetz et al., 1975, as cited in Appendix C). This is an exposure level that some workers exceeded.

It is concluded that workers in the drycleaning industry are potentially at some risk for cancer, and for non-cancer effects. Also, pregnant workers exposed to short-term high PCE levels could be at risk for developmental toxicity.

Uncertainties

The risk conclusions are based on readily available toxicity and exposure data and on models, assumptions, and professional judgements about toxicity and exposure information. These give rise to a variety of uncertainties and assumptions and influence, to a great extent, how close the assessment of risk comes to representing a realistic situation. The factors and uncertainties concerning worker risk conclusions are listed below. Many of these are discussed in more detail in Chapter 4, and Appendices C, D, and E:

- The critical study for the provisional RfC does not permit a quantified dose-response relationship, and does not characterize variability of the exposure concentrations; hence, some lower exposures may still demonstrate the effects.

- It is not clear whether the relationship between PCE dose and human cancer response is best represented by the linear-at-low dose response model used.

- The relevance of animal cancer studies to human carcinogenicity, and whether the mechanism of action of PCE in animals is comparable in humans is under discussion.

- It is not known how representative the occupational exposure studies are of actual exposures to drycleaning workers nationwide. Since the OSHA data are gathered from compliance inspections and compliant investigations, the measurements may not be representative of "average" exposures.

- There are gaps in the human data for developmental and reproductive toxicity, and uncertainties in the animal data, since the study cited included only one dose level.

- The measured Time-Weighted Average samples of PCE may not be representative of the full 8-hour shifts of most workers.

- Variations in the workplace such as machinery maintenance, facility layout, machine controls, work practices, amounts of clothes cleaned daily, and ventilation, may affect an employee's exposure (and hence risk) from PCE. The extremely wide standard deviations in both worker studies may be explained by some of these workplace factors.

5.2.4 Risks to Residents Co-Located with Drycleaning Establishments

Risks from PCE Inhalation

Co-located residents are persons living in the same building as a drycleaning facility that cleans clothes on the premises. The term encompasses children and the elderly as well as adults. Currently it is not known how many persons living in the U.S. are co-located residents. Monitoring studies indicate that persons living in co-located residences are potentially exposed to elevated levels of PCE . Those exposures, however, are not as high as those shown in Chapter 4 for workers. Studies have measured PCE concentrations in apartments above drycleaners in New York, San Francisco, Germany, and the Netherlands (BAAQMD, 1993; NYSDOH, 1993; Schreiber et al., 1993; Wallace et al., 1995). Preliminary

information reported in a recently published abstract (Schreiber et al., 1998) suggests that some body fluid measures of PCE in co-located residents are higher than in control subjects who are not co-located.

Measured concentrations reported in these studies are highly variable, due to a number of factors. These include machine type and condition, machine maintenance, building type, presence of a vapor barrier, small numbers of measurements, and emissions from newly drycleaned clothes stored in the facility (NYSDOH, 1993, 1994). Exposures, and therefore risks from PCE, are expected to vary widely for co-located residents. The wide range of PCE concentrations is shown in Exhibits 4-9 and 4-10. Data are presented by machine type to show their possible significance on measured PCE concentrations.

Monitoring data from four non-overlapping studies of PCE concentrations in U.S. residences co-located with drycleaning establishments were used in assessing exposures and potential for risks to the residents (references listed above). Measurements were taken at different locations, during different seasons, and at different times of the day. (For a detailed discussion of the studies see Chapter 4). Since the studies were conducted under different conditions, they cannot be combined for analysis. However, they can be discussed together qualitatively. Together they give measured PCE concentrations in 62 separate residences co-located with drycleaning establishments.

Exhibit 5-5 illustrates the exposures and relative cancer risk indices for inhabitants of co-located residences. The table lists the average airborne PCE concentrations measured in the four U.S. studies in Column #1. It also indicates which measurements were taken from residences above different machine types. Lifetime Average Daily Concentrations (LADCs) of PCE for adults living in co-located residences are in Column #2. Average LADCs are based on residents' occupying a co-located residence for 2.4 years; high-end exposures are based on an 8-year co-located residency.

Exhibit 5-5. Cancer and Non-Cancer Risks from PCE Associated with Co-located Residences

Study (Number of Residences)	Arithmetic Mean PCE Concentration (mg/m^3) #1	LADC (mg/m^3)[a] #2		Cancer Risk Index[b] (LADC X Unit Risk[c]) #3		Hazard Quotient (LADC / provisional RfC)[d] #4	
		Average 2.4 years	High End 8 years	Average 2.4 years	High End 8 years	Average 2.4 years	High End 8 years
Residences Above Transfer Machines							
Capital District (N=3)	7.72	0.18	0.60	1×10^{-4}	4×10^{-4}	1.1	3.6
New York State (N=1)	15.5	0.36	1.21	3×10^{-4}	9×10^{-4}	2.1	7.1
New York State (N=7)	0.85	0.02	0.07	1×10^{-5}	5×10^{-5}	0.1	0.4
Residences Above Vented Dry-to-Dry Machines							
Capital District (N=1)	0.3	0.007	0.02	5×10^{-6}	1×10^{-5}	0.04	0.12
Capital District (N=1)	45.7	1.05	3.56	3×10^{-3}	$>1 \times 10^{-2}$	6.2	21.0
New York State (N=9)	3.94	0.09	0.31	6×10^{-5}	2×10^{-4}	0.5	1.8
Residences Above Nonvented Dry-to-Dry Machines							
Capital District (N=1)	0.2	0.005	0.02	4×10^{-6}	1×10^{-5}	0.03	0.12
New York State (N=1)	0.75	0.020	0.06	1×10^{-5}	4×10^{-5}	0.12	0.35
Consumers Union (N=29)	1.85	0.040	0.14	3×10^{-5}	1×10^{-4}	0.24	0.82
San Francisco (N=4)	0.25	0.006	0.020	4×10^{-6}	1×10^{-5}	0.04	0.12

[a] LADC (mg/m^3) = Arithmetic Mean PCE Concentration (mg/m^3) x Exposure Duration (ED)/Liftetime (LT)
Expected Duration (ED)
ED = 16.4 hours/day x 365 days/year x 2.35 years (average)
ED = 16.4 hours/day x 365 days/year x eight years (high end)
LT = 24 hours/day x 365 days/year x 70 years
[b] Cancer risk index = upper bound lifetime excess cancer risk
[c] Unit risk = 0.00071 per mg/m^3.
[d] Provisional RfC = $0.17 mg/m^3$

Upper bound lifetime excess cancer risks, as indicated by the risk indices in Column #3 for both average and high-end exposure situations, range from 1 x 10^{-6} (risk of 1 in a million) to >1 x 10^{-2} (>1 in 100). These data show that **in general**, lower exposures were seen in residences above dry-to-dry machines, followed by vented dry-to-dry machines. These are associated with lower risks. The highest exposures (associated with highest risk) were found in residences above transfer machines. However, the one highest exposure level (and highest estimated risk index) indicated in Exhibit 5-5 was measured in the Capital District study in a residence above a vented dry-to-dry machine described as an old unit, "in poor operating condition" (Schreiber et al., 1993). This illustrates that, while both the occupational data and these data for co-located residences indicate higher exposures from transfer machines, machines of any type in poor condition can release high concentrations of PCE.

The data in the table show that all the co-located residences have risk indices greater than 1 x 10^{-6}. These upper bound risks are projected for adults expected to be at home about 16 hours per day. Sub-populations of persons who would spend approximately 23 hours per day at home (which can include infants, children, and the elderly) are estimated to have exposures about 1.4 times those listed in Exhibit 5-5. Currently, we cannot assess whether these sub-populations are more or less sensitive than the population as a whole to PCE exposure.

As a second method of assessing cancer risk for co-located residents, we can use the margin of exposure (MOE) nonprojection ratio approach by comparing their average and high-end Lifetime Average Daily Concentrations (LADCs) with the ED_{10} dose of 270 mg/m^3 [the level in human equivalents at which 10% of the animal study population showed excess tumors]. All of the average LADCs (except for the one machine known to be in poor condition, cited in Schreiber et al., 1993) are close to, or greater than 1,000-fold lower than the ED_{10} dose. (When MOEs are calculated for these "average" co-located residents' exposures, the MOEs range from 750 to 54,000, indicating a fairly large to very large margin from exposure to effect level.[3] This is also true for the high-end LADC co-located residents (those who spend at least 8 years in the same residence), although the MOEs are lower, especially for residents above transfer machines (MOEs range from 223 to 13,500).

Column #4 in Exhibit 5-5 gives hazard quotients (HQs) for non-cancer effects for average (2.4 years' residence) and high-end (8 years' residence) exposures for the co-located residents. HQ values above 1 indicate a concern for non-cancer effects. The data presented in the table indicate concerns for non-cancer risks to co-located residents living above transfer machines and vented dry-to-dry machines, but not above nonvented dry-to-dry machines, regardless of duration of residence. This concern for risk would also be true for infants, children, and the elderly living in the same residences, whose exposures are estimated at about 1.4 times that of the adults in general. Data are not currently available to evaluate whether these sub-populations are more or less sensitive than the population as a whole to non-cancer effects caused by PCE.

[3]Sample MOE calculation: ED_{10}/LADC = 270 mg/m^3/0.18 = 1,500.

Risks from Dermal Exposures

As mentioned in the section on occupational risks, dermal absorption can occur from PCE vapor in the air. There are limited data to suggest that the amount absorbed dermally can be equal to the amount absorbed via inhalation at relatively low levels.

Combined Risks

The health risks to co-located residents from PCE are usually considered the sum of all risks due to exposures through all major routes of the body. Data were available to give an indication of PCE exposures through inhalation. No equivalent data were available for dermal exposures. It is possible that an equivalent amount of PCE vapor could also be absorbed into the body through the skin. [This would increase the mean exposure numbers listed in Exhibit 5-5, but the risk indices would still be of the same order of magnitude].

The PCE exposures to the general population through such means as drinking groundwater, showering and bathing, wearing drycleaned clothes, or taking them into the home, would also apply to co-located residents. Risks from these exposure scenarios are discussed in the next section which deals with general population risks. These general population risks would be added to the risk associated with co-residency.

Risk Conclusions—Co-located Populations

There is concern that there can be a cancer risk to residents living in co-location with PCE drycleaning establishments, particularly if they live in such dwellings for several years (indicated by high-end risk indices). The cancer risk indices generally show rates higher than one in a million. The data show that exposures and associated upper bound lifetime excess cancer risks appear to be higher for residents living above transfer machines, although use of poorly maintained dry-to-dry machines also causes high exposures. There is also concern for risk for non-cancer effects. Adults in residences above nonvented dry-to-dry machines appear to have lower exposures. Co-located residents are also at risk through a variety of PCE exposures that the general public experience, in addition to their exposures related to co-location with drycleaning facilities. Risks potentially experienced by the general population, such as drinking PCE-contaminated water, or wearing drycleaned clothes, would be added to the risks due to co-location. Children, infants, and the elderly, who spend most of their day in the residence, may be at slightly greater risk than adults in general for both cancer and non-cancer effects due to increased exposure duration.

As stated previously, the cancer risk analysis approach (unit risk) is tied to an upper bound lifetime excess cancer risk estimate and there is the possibility that the lower bound is as low as zero.

Uncertainties

The risk conclusions are based on readily available toxicity and exposure data and on models, assumptions and professional judgements about toxicity and exposure information. These give rise to many uncertainties and assumptions and influence, to a great extent, how close the assessment of risk comes to realistic representation. In addition to uncertainties regarding the evaluation of PCE's toxicity, which are enumerated in the section on occupational risks, selected prominent factors and uncertainties

concerning conclusions regarding co-located residents' risk are listed below. Many of these are discussed in more detail in Chapter 4, and appendices C, D, and E:

- It is not known whether the exposure data presented can successfully represent co-located residents nationwide, or whether there are major regional or local differences.

- Although conclusions about exposures are based on four U.S. studies, these studies were carried out under different circumstances and may only be regarded individually. Each study in itself is relatively small, and the complaint investigations may not adequately characterize exposure comparisons between machine types.

- Although we discuss risks for residents exposed to estimated arithmetic mean PCE concentrations, there is uncertainty as to what the mean concentration value is, since the individual exposure studies show large variations (standard deviations).

- It is not clear whether the short-term sampling done in some of the studies may have missed major fluctuations in exposures.

- It is not clear whether significant numbers of residents stay in their apartments for more than 8 years, or fewer than 2.4 years.

- In certain studies, the presence of drycleaned clothes in the residences may have added to measured air concentrations.

5.2.5 General Population Risks

Risks from PCE Inhalation

In the mid-1980s, USEPA characterized general population exposures to a selected slate of chemicals in four urban areas. The Total Exposure Assessment Methodology (TEAM) study reported 24-hour concentrations of PCE from close to 1,000 personal samples of persons living in New Jersey, California, Maryland, North Dakota, and North Carolina (Wallace, 1989). The monitored persons were chosen to represent members of the general population in these areas. No persons in co-located residences were included in the study.

This study was chosen for use in assessing risk for the CTSA because of its size, coverage of several states, and personal sampling of people's indoor and outdoor exposures over several days. The TEAM study hypothesized that the PCE exposure levels of the persons measured were due not only to ambient air, but also due to PCE exposures from visiting drycleaning shops, wearing and being exposed to others wearing drycleaned clothes, transporting and storing drycleaned clothes, and PCE from non-drycleaning sources.

Exhibit 5-6 illustrates the exposures and risk indices associated with the residents' 24-hour inhalation of combined indoor and outdoor air in a typical home not in proximity to a drycleaning shop. The first entry in Column #1 in the table gives the Lifetime Average Daily Concentration of PCE for the general population based on the 24-hour personal sample average exposures of the persons in the TEAM

study (0.017mg/m^3). The CTSA exposure assessment (Chapter 4) assumed this exposure to be constant over a lifetime (to be the Lifetime Average Daily Concentration). Therefore, it is listed as the LADC. Average outdoor ambient air was measured in the TEAM study as 0.003 mg/m^3, and was also assumed to be constant over a lifetime. It is listed in the second entry in Column #1 of the table as the LADC, serving as a background level.

Exhibit 5-6. General Population Cancer and Non-Cancer Risks from Inhalation of PCE

Exposed Population[a] (24 hour exposure)	LADC (mg/m^3) #1	Cancer Risk Index[b] LADC x Unit Risk[c] #2	Hazard Quotient LADC/Provisional RfC[d] #3
General Population-Adults (daily activities indoors & outdoors)	0.017	1. 2 x 10^{-5}	0.1
Ambient Air	0.003	2 x 10^{-6}	0.02

[a] TEAM Study, 1989
[b] Cancer risk index = upper bound lifetime excess cancer risk.
[c] Inhalation Unit Risk = 0.00071 per mg/m^3
[d] "Provisional RfC" = 0.17mg/m^3

Exposures and corresponding cancer risk indices to the general population are lower than those in most co-located residences (Exhibit 5-5), but are higher than PCE levels measured in ambient outdoor air alone from the TEAM study . The calculated risk index of 1.2 x 10^{-5} for the general population seen in Column #2 is above that from exposure to ambient air alone (2 x 10^{-6}).

The LADCs for both the general population and ambient air are more than 1,000 times lower than the ED_{10} of 270 mg/m^3 [the level in human equivalents at which 10% of the animal study population showed excess tumors]. These MOE nonprojection ratios indicate a large margin between expected exposures and the effect level.[4]

Column #3 in Exhibit 5-6 shows the hazard quotients for non-cancer effects. The HQs are below 1, indicating lowered concern that deleterious effects will occur.

Risk from PCE Ingestion

Exhibit 5-7 illustrates potential risks from exposures to PCE-contaminated water. The exposure scenario for drinking water ingestion is based on measurements of PCE in contaminated groundwater from two independent studies, Izzo (1992) and Stasiuk (1993). The California Regional Water Quality Control Board took measurements from more than 215 wells, most of which were large system municipal wells. Many wells contained PCE in excess of 5 ppb (parts contaminant per billion parts of water), California's maximum contaminant level (MCL). The New York State Department of Health has also reported PCE

[4]LADC compared with ED_{10}: MOE= 270 mg/m^3/0.017 mg/m^3 = 15,882

concentrations in groundwater in public and private wells. They measured PCE in eight public wells at concentrations from 61 to 640 ppb. (See Chapter 4 for further discussion.)

Exhibit 5-7 lists Lifetime Average Daily Doses (LADDs) calculated for individuals assumed to drink 1.4 liters of PCE-contaminated water each day. (See Exhibit 5-7 footnote LADD sample calculation.) It was assumed for this CTSA that PCE contamination of municipal wells would be kept at or below the 5 ppb maximum contaminant level (MCL). The range of the LADDs presented in Exhibit 5-7 would be the lifetime average daily dose expected from drinking water contaminated with PCE at a low of 0.8 ppb to the 5 ppb MCL. The cancer risk indices are also presented as a range from 1×10^{-7} to 5×10^{-7}. Therefore, if PCE contaminant levels are kept below the MCL of 5 ppb, cancer risks would be low. The last column in the table presents hazard quotients (HQs) for non-cancer effects for the high and low end of the exposure range from 0.8 to 5 ppb PCE contamination. The very small HQs suggest low risk for non-cancer toxicity to the public from drinking well water contaminated at these levels.

Exhibit 5-7. Cancer and Non-Cancer Risks from Exposure to PCE-Contaminated Drinking Water

Exposure Scenario	LADD[a] (mg/kg/day) Range	Cancer Risk Index[b] (LADD x Unit Risk[c]) Range	Non-Cancer Oral Hazard Quotients[d] (LADD/RfD)
Potential Risks from PCE-Contaminated Drinking Water - PCE in ground water	0.000002 to 0.00001	1×10^{-7} to 5×10^{-7}	0.0002 to 0.001

[a] LADD = Lifetime Average Daily Dose
LADD = [PCE] x 1.4 liters x 9 years/70 years x 1/72kg
where [PCE] = PCE concentration in drinking water in mg/L
[PCE] = 0.0008 mg/L
1.4 liters = Average adult consumption of drinking water
70 years = Average lifetime
72 kg = Average adult weight
[b] Cancer risk index = upper bound lifetime excess cancer risk
[c] Oral Unit Risk = 0.051 per mg/kg/day. Sample Calculation, Risk Index = 0.0001 mg/kg/day X 0.051 per mg/kg/day = 1×10^{-7}
[d] RfD = 0.01 mg/kg/day.

Risks from Dermal Exposures

Exposures (and consequently risks) could also result from bathing or showering in water contaminated with PCE. Dermal uptake of PCE in bath water has been estimated to equal the dose received from drinking two liters of water a day (Riihimaki et al., 1978; McDougal et al., 1990; Bogen et al., 1992; in Keifer, 1998). Therefore, the estimated risk indices from dermal exposures by daily bathing in PCE-contaminated water would be somewhat similar to those presented in Exhibit 5-7 for drinking 1.4 liters of PCE-contaminated water a day.

The HQs for drinking PCE-contaminated water are well below one; thus, expected risks from dermal exposures from bathing/showering are low for toxicities other than cancer.

Combined Risks from Other Routes

The health risks to the general population from PCE are regarded as the sum of the individual risks due to exposures through all major routes of the body. Therefore, if persons in the general population are also exposed to PCE from contaminated drinking water, shower or bath water, risks from those exposures would be added to the risks from inhalation of PCE.

Risk Conclusions—General Population

If the general population were exposed to PCE via inhalation for its lifetime at the average daily level measured in the TEAM study, there can be a concern for risk of cancer, albeit much lower than either the occupational or co-located resident scenarios described earlier. There would not be a concern for non-cancer health risks. However, it is not possible to generalize from the data that the individuals in the general population of the United States would be exposed at these levels for a lifetime.

If PCE contaminated drinking water is at or below the MCL of 5 ppb, there would not be a concern for health risks to the general public. Although higher PCE levels have been measured in private and municipal wells, it is assumed for this CTSA that PCE levels in excess of the MCL would be remediated so that contamination would not be present in drinking water on a long-term basis.

Uncertainties

The risk conclusions are based on readily available toxicity and exposure data and on models, assumptions and professional judgements about toxicity and exposure information. These give rise to many uncertainties and assumptions and influence to a great extent how closely the assessment of risk represents reality. Prominent specific factors and uncertainties concerning general population risk conclusions are listed below. These and other factors are discussed in more detail in Chapter 4, and Appendices C, D, and E:

- The risk conclusions for the inhalation exposure scenario are based on a single study's exposure estimates. The TEAM study is 10 years old, took measurements over a short time, and focused on persons living in several states across the country. It is uncertain how well this study represents the actual PCE exposures to the general population throughout the United States.

- The TEAM study results included a single, unusually high measured concentration from North Dakota. Since the TEAM study results included this measurement in the calculation of the arithmetic mean concentration, it has been included in the CTSA as well. Wallace (1989) stated that if this measurement were not used, the arithmetic mean concentration would have been 0.012 mg/m^3. The general population's overall LADC then would have been 0.012 mg/m^3, and the associated risk index 2×10^{-6}.

- The two groundwater studies show considerably differing measurements of PCE contamination. It is not known how representative the studies are of groundwater contamination throughout the United States.

- A major uncertainty is whether, in fact, PCE contamination of municipal and private drinking water wells is kept at or below the MCL of 5 ppb.

- The estimates of lifetime average daily dose of PCE from contaminated drinking water used in the CTSA could be conservative since they do not take into account that household water supplies may be drawn from a number of different wells; and they assume there is no PCE removal during treatment.

- The estimates of ingestion exposure assume that there is daily exposure to the PCE contaminated water over a lifetime. It is not known whether this is the case for the general population.

- The inferences regarding potential for dermal exposures are based on very limited data.

5.2.6 Special Sub-populations

General

The data available for this CTSA do not adequately permit addressing the question of whether health risks due to PCE exposures differ significantly between such special sub-populations, as infants, children, the elderly, and adults in general. Therefore, risks to sub-populations from PCE exposures are considered the same as for adults in general unless there is specific information to the contrary. There is a lack of data concerning:

(1) The toxicity of PCE to different sub-populations compared with adults as a whole (i.e., whether different sub-populations or groups are more susceptible, or less susceptible to the carcinogenic and non-carcinogenic effects of PCE). We currently have no information as to whether PCE is more or less carcinogenic or otherwise toxic to infants, children, or the elderly. The RfD/RfC concept incorporates the idea that a 24-hour exposure over a lifetime at the designated level generally is not expected to be toxic to the general public, including sensitive sub-populations. Therefore, in this CTSA the measures of toxicity (cancer unit risk, RfD/RfCs) used for adults are also used for all sub-populations.

(2) The PCE exposures of different sub-populations compared with adults as a whole. (i.e., whether different sub-populations or groups are exposed to PCE at higher or lower levels than adults in the general population.) There are some indications that certain sub-populations differ from adults in their exposures to PCE. This may be indicative of their different exposure patterns throughout the day. These patterns are mentioned in the discussion of co-located residences. Infants, children, and the elderly on the whole are thought to spend more time in the co-located residence than adults in general, resulting in an estimate of about 1.4 times the exposures of PCE for them than for those adults. Therefore, their risks are derived using the higher exposure level.

Infants

Several models have been developed to estimate the amount of PCE to which an infant is exposed through ingesting breast milk that contains PCE. One model predicted infant exposures would range from

0.0001 to 0.92 mg/kg/day (Schreiber, 1997). Another model (Fisher et al.,1997) estimated infant exposure at 0.34 mg/kg/day. These models and their background information are discussed in more detail in Chapter 4.

One estimate of infant exposure was made for a hypothetical situation in which a woman is exposed at work to PCE at the OSHA Permissible Exposure Level of 25 ppm and then breast feeds her infant. The infant was estimated to ingest 1.36 mg/day of PCE. That author concluded that this would result in a health risk since the infant's exposure would exceed an EPA Health Advisory Intake of 1.0 mg/day. [The Health Advisory is set by the USEPA Office of Water for chronic ingestion of contaminated water by 10 kg children, assuming ingestion of 1 liter of water per day (Fisher et al, 1997)]. Schreiber (1997) concluded that the benefits of breast feeding outweigh the risks; and also estimated that the majority of an infant's PCE exposure results from inhalation rather than ingestion.

It is beyond the scope of this CTSA to properly evaluate these pharmacokinetic models given their complexity in design and assumptions. Further, even with an estimate of PCE delivered by lactation, there is no cancer model or non-cancer comparison value adapted for use with infant exposures. Therefore, no attempt is made to utilize estimated exposures for quantifying potential health risks to infants. Qualitatively, there appears to be a potential for health risks to infants in situations where they are exposed to levels of PCE which are also a concern for the adult population. This could be via inhalation, dermally, or through ingestion. Exposure scenarios which appear to be of most concern for risk for infants are those providing inhalation of PCE-contaminated air in co-located residences, and ingestion of contaminated breast milk.

Children/Families

There have been some studies suggesting that families of drycleaning workers may experience elevated PCE concentrations in their homes, and it has been hypothesized that workers introduce PCE into their homes through their exhaled breath. (Thompson and Evans, 1993; Aggazzotti et al.,1994). The information is of interest (see Chapter 4) and suggests a specific exposure scenario through which children might be at additional health risk from PCE.

Summary

Adult risk does not translate directly to infants, children, and the elderly. In scenarios where high risk indices have been inferred at high exposure levels for adults in general, however, there should be concern for sub-populations exposed by similar routes at similar exposure levels.

5.2.7 Environmental Risk

Risk to Aquatic Organisms

A PCE concern concentration (CC) for aquatic organisms was determined by dividing the lowest chronic toxicity value for PCE, 0.66 mg/l for daphnids (Chapter 3, Exhibit 3- 2), by an assessment factor[5] of ten. The CC of 0.07 mg/l is the concentration of PCE in surface water above which toxic effects may occur to aquatic organisms. The greater the exceedence and the longer the CC is exceeded, the greater the probability of toxicity to aquatic organisms.

If effluent (wastewater) flows from drycleaning facilities are sent to Publicly Owned Treatment Works (POTWs), the estimated PCE concentration in water, 3 ppb (see Section 4.4.1) is expected to be well below the concern concentration of 0.07 mg/L (70 ppb). If effluent flows are not sent to a POTW, it is possible that PCE could be present in surface water in excess of the CC. Anecdotal data suggest, however, that most drycleaners discharge their effluent to a POTW.

Surface water contamination by PCE has been found in many locations throughout the U.S., with PCE concentrations ranging from a fraction of a part per billion to hundreds of thousands of parts per billion. Of course, these levels are due to all sources of PCE and not just from drycleaning establishments. In this assessment, only surface water concentrations in which the contaminating source was identified as a drycleaning facility were used (General Population Exposure Assessment).

Risk Conclusions

The concern concentration (CC) for aquatic organisms for PCE is not exceeded, and therefore, there is low risk to aquatic species for the majority of drycleaners who send their wastewater effluents to a POTW. Drycleaning establishments that do not send their wastewater effluents to a POTW may cause surface waters to exceed the PCE CC, and therefore put aquatic organisms at risk.

Uncertainties

There are uncertainties connected with using the Structure-Activity-Relationship (SAR) methodology (see Appendix B) for calculating the concern concentration. However, the combination of cross-checking the PCE literature and the extent of the PCE database, as well as the history of usage of this technique, increases the belief that this concentration predicts toxicity to aquatic organisms well.

There are uncertainties as to actual surface water levels, since estimated levels are based on estimated wastewater releases from drycleaning establishments, and the assumption that most establishments send effluent wastewaters to a POTW with subsequent further PCE removal.

[5]Assessment factors incorporate the uncertainty associated with (1) toxicity data--laboratory tests versus field tests and measured versus estimated data; and (2) species sensitivity. Assessment factors range from 1,000 to 1 depending on the amount and quality of available aquatic toxicity data. Because the hazard profile for PCE contained three chronic SAR values (in addition to one measured and two SAR acute values), an assessment factor of 10 was used (for a full explanation, see Appendix B).

Other Environmental Effects

PCE is not a stratospheric (higher atmosphere) ozone depleter, because it is destroyed in the troposphere (lower atmosphere, or a region of the atmosphere extending to between eight and sixteen kilometers above the earth's surface). In the troposphere, PCE undergoes photochemical degradation to the extent that its estimated lifetime is appreciably less than one year (Appendix A).

5.2.8 Human and Environmental Risks—Overall Summary and Conclusions

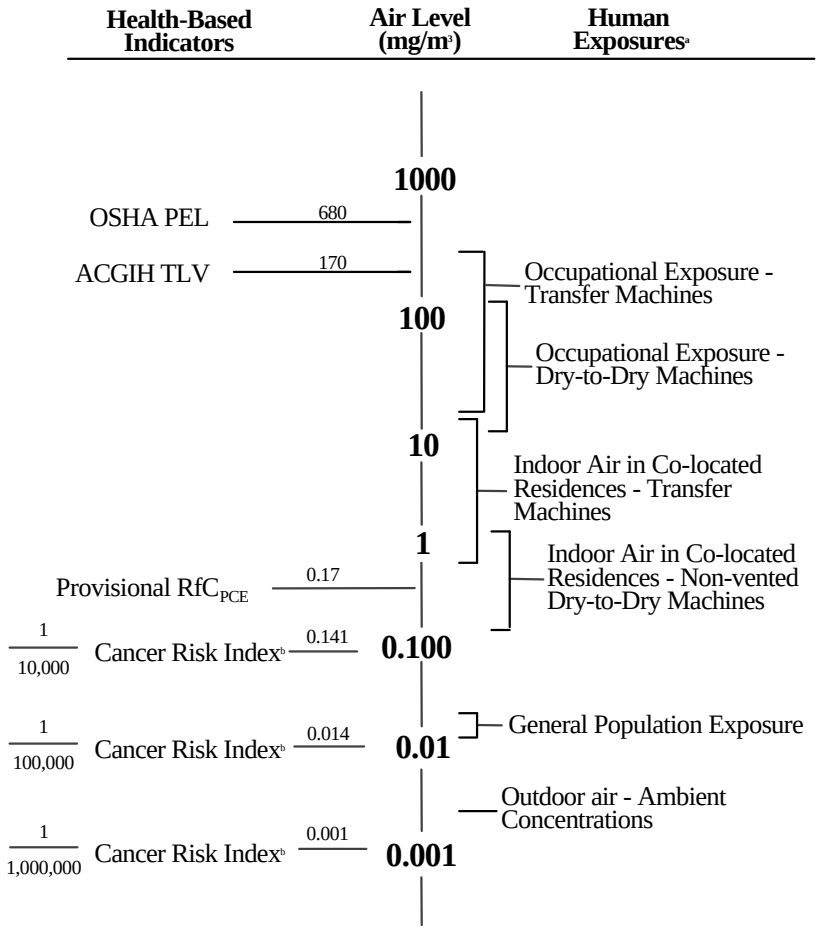
Exhibit 5-8 summarizes in a graphical format the human health hazards of PCE and the inhalation exposures associated with its use as a drycleaning solvent. Two exposure scenarios stand out as the highest levels of concern: occupational exposure to drycleaning workers and exposure to residents (including children) of dwellings located above drycleaning shops. There is a potential concern for cancer and non-cancer toxicity risks to workers exposed to average PCE levels measured in drycleaning facilities. There are also qualitative data supporting a concern for developmental toxicity risk to workers exposed to the high end PCE concentrations measured in the workplace. Exposures and, consequently, risks tend to be higher if transfer machines are used instead of dry-to-dry machines, but there are still health risks associated with PCE exposure levels from dry-to-dry machines. Worker PCE exposures appear highly variable, which may be due to such diverse factors as differences in facility layouts, machine maintenance, machine controls, amount of clothes cleaned, and ventilation. Workers can also be exposed to PCE via dermal exposures, either directly through contact with the liquid, or skin contact with PCE vapor. Risks to workers by this exposure route would be added to risks due to inhalation exposures.

Residences above shops with transfer machines typically have airborne PCE concentrations 10- to 100-fold lower than the occupational scenarios. There is concern for cancer and non-cancer risks to these residents who live co-located with drycleaning facilities. Such residents include infants, children, and the elderly, as well as adults. Residences above non-vented dry-to-dry machines tended to have lower PCE exposures than those above transfer machines and were at the lower end of the exposure range. Some measured levels in such residences are not much higher than ambient indoor air in homes not co-located near drycleaning shops. However, limited data indicate that high exposures can occur even with dry-to-dry machines if they are poorly maintained.

Sufficient data are not available to make quantitative risk conclusions concerning exposures to special sub-populations such as infants, children, and the elderly. As a rule of thumb, however, exposure scenarios where health risks are of concern for adults should be considered to be of concern for health risks to these sub-populations. Models have been developed to predict levels of PCE ingested by infants from contaminated breast milk. This is a possible scenario for a health risk to infants.

Measured ambient air levels of PCE are low, but the general population can be exposed to PCE from a variety of sources in addition to ambient air, such as from visiting drycleaning establishments; bringing home and storing dry-cleaned clothes; wearing dry-cleaned clothes; being exposed to others' dry-cleaned clothes; and drinking and bathing in contaminated well water. Limited data indicate that these exposures can increase average exposures several times over ambient levels. Exposures from inhalation, ingestion, and through the skin would be additive.

Exhibit 5-8. PCE Hazards and Inhalation Exposures



[a] Concentrations are arithmetic means. Therefore, the brackets do not reflect the entire range of concentrations found in any particular study.

[b] Based upon linear-at-low dose approach with a unit risk value of 0.00071 per mg/m^3.

Health risks to aquatic organisms are expected to be low if drycleaning wastewater effluents are sent to (POTWs). This is expected to be the case for most drycleaning establishments. If, wastewater effluent is not sent to a POTW, there could be health risks to aquatic organisms from PCE concentrations in surface waters exceeding the concern concentration. Health risks to terrestrial organisms were not evaluated.

Some yet-unanswered key issues surrounding the assessment of risks due to PCE used during the drycleaning processes are:

- whether PCE causes cancer in humans at low doses, and what its mechanism of action is;
- do the various models used to estimate PCE exposures in nursing infants present realistic estimates of exposures;
- does PCE cause developmental toxicity in humans, and if so, at what concentrations; and
- what is the true range of exposures to PCE experienced by co-located residents throughout the country?

5.3 DRYCLEANING USING HYDROCARBON (HC) SOLVENTS

5.3.1 Human Health

Hydrocarbon (HC) solvents (Stoddard solvent, 140°F solvent, and DF-2000) may be used to dryclean clothes. In this CTSA, hazard information (Chapter 3) on Stoddard solvent is assumed to represent all three solvents. Exposure information (Chapter 4) is available for Stoddard solvent and 140°F solvent. Both Stoddard and 140°F solvents are mixtures that consist of linear and cyclic paraffins with total carbons varying from C9 to C12. The constituents and their percentages vary.

A major hazard identified with the HC solvents considered in the CTSA is their potential flammability (Chapter 3). The National Fire Protection Association (NFPA) gives HC solvents a ranking of “2” for flammability, indicating that they must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. For comparison, perchloroethylene receives a ranking of “0” for flammability, which indicates that it will not burn (Ahrens, 1998).

5.3.2 Human Health Risks

Risk—General

In this section, the hazards and individual exposure scenarios are integrated to address the potential risks of hydrocarbon (HC) solvents. Stoddard solvent will be used, for risk assessment purposes, to represent HC solvents in the drycleaning industry. There is evidence indicating that Stoddard solvent is absorbed into the body via inhalation, the gastrointestinal tract, and through the skin. There are some human data indicating that it can cause neurotoxic effects, and is an irritant to the eyes, mucous membranes, and skin. Kidney toxicity (see Appendix C) has also been reported in animal studies.

There were no data suitable for drawing conclusions concerning the carcinogenic potential of Stoddard solvent, so no expression of risk is made for cancer. No cancer unit risk or slope factor has been established. Also, no oral RfD or inhalation RfC has been established to date for Stoddard solvent or any other HC solvent.

For the purposes of the CTSA, a non-cancer comparison value was derived from an animal study (see Chapter 3 and Appendix C) for a discussion of the spectrum of effects associated with Stoddard solvent. The comparison value was taken directly from a 13-week study in male rats (Carpenter et al., 1975a, 1975b, see Appendix D). A No-Observed-Adverse-Effect Level (NOAEL) was identified as 480 mg/m^3 with recognition that it is not from the usual chronic study. [Note: The American Conference of Government Industrial Hygienists, ACGIH has established a Threshold Limit Value (TLV) guideline for Stoddard solvent exposure in the workplace of 525 mg/m^3 (100ppm) (ACGIH, 1996)].

Routes of Exposure

Inhalation

Inhalation is the likely route of exposure to HC solvents based on their physicochemical characteristics (Appendix A). Stoddard solvent, the HC solvent reviewed in Chapter 3, is readily absorbed from the lung following inhalation exposure.

Oral

There are no data on the oral absorption rate of Stoddard solvent. Based on studies of other petroleum distillates, it is judged that the rate and extent of gastrointestinal absorption of Stoddard solvent is likely to depend on the lipophilicity and size of its various components and the amount of food in the stomach.

Dermal

Dermal absorption is expected to occur, but there is no information on the rate of absorption. Stoddard solvent was found to be dermally absorbed by rats, and by analogy, there should be some absorption through human skin.

5.3.3 Occupational Risks—Drycleaning Workers

Risks from HC Solvent Inhalation

HC solvents are used much less often than PCE in commercial drycleaning, and less information is available for them. The number of workers exposed to hydrocarbon (HC) solvents in facilities that dryclean clothes is estimated to be between 21,000 and 49,000 (Chapter 4) . The most significant route of exposure for workers is expected to be from inhalation, although they may also be exposed through the skin. Only a few studies and data sets are available to characterize inhalation exposures to HC solvents. These are presented and discussed in Chapter 4. Inhalation exposures and consequently, potential risks from HC solvents to workers, are expected to be higher than for any other exposure group.

The two data sets available for exposure estimates are from OSHA air monitoring data for the years 1990-1993 and 1997 (OCIS,1994,1998), and from a pre-1980 NIOSH survey (NIOSH,1980). They are presented in Chapter 4. The OSHA data include a set of 28 inhalation exposure samples listed by worker job category. An additional 11 samples were obtained for 1997, for the category "all jobs." The NIOSH survey was of 6 drycleaning facilities, ranging from very small to a large industrial facility, and exposures were listed by worker job categories.

As in the case of PCE, there are differences in exposures and risks to workers in different job categories. Limited exposure data give an indication that persons in the job classification "cleaner" (equivalent to "operator") may be the most exposed to HC solvents via inhalation.

To get a general estimate of non-cancer risks to workers, we can use the exposure levels measured (arithmetic mean as average and maximum as high-end) from the OSHA and NIOSH studies (see Exhibits 4-11 and 4-12) to represent worker exposures in the commercial drycleaning industry, and compare these exposure levels with the toxicity comparison value of 480 mg/m^3 as a NOAEL for non-cancer toxicity. In most cases, (except for job categories "presser" and "customer service") there was not a large difference between the NOAEL from the animal study and worker lifetime average daily exposures. Worker average exposures ranged from about 5- to 120-fold lower than the animal NOAEL of 480 mg/m^3. Worker high-end lifetime average daily exposures were about 2- to 50- fold lower than the comparison value. These exposures to HC solvents, especially the high-end ones, are indicative of a potential concern for non-cancer risk for workers. (A sample calculation of the LADC and comparisont with the NOAEL is presented using OSHA 1997 data from Exhibit 4-11 for "all jobs".[6])

Risks from Dermal Exposure

Although there is potential for dermal exposure to HC solvents as with PCE, there are no data to assess the potential magnitude of dermal exposures. Dermal exposures can be modeled, however, and those procedures are discussed in Chapter 4. Dermal exposures can be from direct contact with liquid HC, and also possibly with the HC vapor. The risks from dermal exposures would be added to the risks indicated for inhalation.

Combined Inhalation and Dermal Risks

The health risks to drycleaning workers from HC solvents depend on the solvent entering the body through two major routes of entry—inhalation and through the skin. (Oral, hand-to-mouth exposure is not

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[6]LADC = Exposure x 10 m^3/20m^3 x 250 days/365 days x 40 years/70 years

10 m^3 = Volume of air inhaled during an 8 hr workday
20 m^3 = Volume of air inhaled in 24 hours
250 days = Days worked per year
365 days = Days per year
40 years = Years worked in a lifetime
70 years = Average lifetime

The "All Jobs" arithmetic mean = 150 mg/m^3, , therefore using the formula above, the LADC = 29 mg/m^3.
This LADC is about 17-fold less than the NOAEL of 480 mg/m^3

considered a major route, but if it occurs would also be added to the total risk). Dermal exposures would be added to the overall risks estimated from inhalation exposures, although inhalation is expected to be the dominant route of exposure.

Risk Conclusions

There is a reasonable basis to conclude that there can be a health risk for non-cancer toxicity to workers from the relatively high HC solvent exposures observed in the drycleaning industry. This conclusion is based on monitored worker inhalation exposure data from several sources, from information about circumstances for dermal exposures in the workplace, and the potential for Stoddard solvent to absorb through the skin, combined with evidence from animal studies indicating that Stoddard solvent can be toxic in laboratory rodents. Monitored worker inhalation exposure concentrations, especially at maximum exposure concentrations were close to the toxicity comparison NOAEL.

It was not possible to quantify the risk of fire in this CTSA. However, the risk for fire is an important concern for the HC solvents and would be a greater risk for the HC solvents than for PCE based on their higher flammability rating.

Uncertainties

The risk conclusions are based on readily available toxicity and exposure data and on models, assumptions, and professional judgements about toxicity and exposure information. These give rise to many uncertainties and assumptions and influence, to a great extent, how close the assessment of risk comes to realistic representation. Some central factors and uncertainties concerning worker risk conclusions are listed below. Many of these are discussed in more detail in Chapter 4, and Appendices C, D, and E:

- There is not a sufficient database to indicate whether Stoddard solvent or other HC solvents are carcinogenic in humans or animals. Epidemiologic studies reporting associations of certain cancers with mineral spirits' exposure could not separate this exposure from others sustained by the cases. It is not clear what might be seen if HC solvents were used more widely.

- It was not possible to develop and review a provisional RfC for this CTSA. Therefore, a comparison was made with a NOAEL directly from an animal study. This toxicity comparison value has not had the level of review that the provisional RfC for PCE has had, and therefore there is a greater level of uncertainty as to its validity. The toxicity comparison value may be higher or lower than the one that a USEPA Agency-wide analysis of a more extensive database might select.

- It is not known how representative the occupational exposure studies are of actual exposures to drycleaning workers nationwide. Since the OSHA data are obtained from compliance inspections and complaint investigations, the measurements may not represent "average" exposures. The NIOSH data were collected almost 20 years ago (pre-1980) and may not represent current exposures. Also, they included exposures from industrial drycleaning settings which may not be representative of the commercial drycleaning industry.

- The measured time-weighted average samples of Stoddard solvent may not represent well the full 8-hour shifts of most workers.

- Variations in the workplace, such as machinery maintenance, facility layout, machine controls, work practices, amounts of clothes cleaned daily, and ventilation may affect an employee's exposure (and hence risk) from HC solvents. The extremely wide standard deviations from the mean exposure levels in both worker studies seen in Exhibits 4-11 and 4-12 may be indicative of some of the workplace factors listed here.

5.3.4 General Population Risks—Residents Co-Located with Drycleaning Establishments

It is possible that co-located residents have potential ambient air exposures to HC solvents, and therefore would have health risks. Although no data were available for this exposure scenario, and therefore, no further discussion of risk is considered in the CTSA, the reader may compare the relative magnitudes of worker scenarios between PCE and the HC solvents, and take into account the possibilities for co-located residents exposures to HC solvents.

5.3.5 General Population Risks

Risks from HC Solvent Inhalation

There were no data available for actual ambient air exposure levels for the general population exposed to HC solvents. In this case, therefore, several hypothetical exposure scenarios for potential inhalation exposures were modeled for the general population. Exhibit 4-13 presents a "what-if-exposure scenario," which assumes that HC solvent would be released to air continuously, and expose people at nearby homes to HC vapors throughout the day over a period of 9 years (considered to be the average time spent in any one residence). It gives estimated Lifetime Average Daily Concentrations of HC solvent to such persons. (These would include infants, children, the elderly, and other adults). The exposure scenarios include exposures from facilities 100 meters to 400 meters away, with transfer or dry-to-dry machines.

If the modeled worst case (i.e., a transfer machine releasing HC solvent at a distance of 100 meters from the general population) general population exposure level listed in Exhibit 4-13 is compared to the toxicity comparison value of 480 mg/m^3 for a NOAEL for non-cancer toxicity, it can be seen that the estimated general population lifetime exposure is 240,000 times lower than the NOAEL. This would therefore, suggest low concern for non-cancer health risk.

Risks from HC Solvent Ingestion

There is a lack of information concerning the HC solvents in groundwater; however, it is thought that the migration potential of HC solvents to groundwater is negligible. The estimated drinking water exposure to the general population is very low—much less than one mg per kg per day (Chapter 4), and therefore, risks are estimated to be very low.

Risk Conclusions

Chronic health risks to the general population from estimated inhalation exposures to HC solvents are considered low. Risks from ingesting drinking water contaminated with HC solvents are also considered low, given the very low projected releases of HC solvents to surface waters. These conclusions are based on modeled exposure scenarios combined with evidence from animal studies indicating that Stoddard solvent can cause toxicity in laboratory animals and were hampered by lack of actual exposure data.

Uncertainties

The risk conclusions are based on readily available toxicity and exposure data and on models, assumptions, and professional judgements about toxicity and exposure information. These give rise to many uncertainties and assumptions and influence to a great extent how close the assessment of risk comes to realistic representation. Some central factors and uncertainties concerning general population risk conclusions are listed below. Many of these are discussed in more detail in Chapter 4, and Appendices C, D, and E. The same uncertainties hold as to the limitations of the toxicity database as are indicated in the Uncertainties section on risks from occupational exposures.

- Using models to estimate potential general population airborne exposures and concentrations in drinking water necessitates many assumptions, and therefore introduces uncertainties regarding the closeness of these estimated exposures to reality.

- There are uncertainties as to the actual surface water levels, since estimated levels are based on estimated wastewater releases from drycleaning establishments, and on the assumption that most establishments send effluent wastewater to a POTW with subsequent HC solvent removal.

- Hazard and most of the exposure information are based only on Stoddard solvent. Other HC solvents may differ somewhat.

5.3.6 Special Sub-populations

General

As was the case with PCE, the data available for this CTSA do not provide an answer to the question of whether health risks due to HC solvent exposures differ significantly between special sub-populations, such as infants, children, the elderly, and other adults. Therefore, risks to special sub-populations from HC solvent exposures should be treated the same as for the broad class of other adults unless there is specific information to the contrary. Information regarding items (1) and (2) below may permit future estimations of risk.

(1) The toxicity of HC solvents to infants, children, and the elderly compared with other adults (i.e., whether these different sub-populations or groups are more susceptible, or less susceptible to the toxicity of HC solvents.) We currently have no information on this.

(2) The HC solvent exposures of these different sub-populations compared with adults in general (i.e., whether different sub-populations or groups are exposed to HC solvents at

higher or lower levels than adults in the general population.) Infants, children, and the elderly on the whole may spend as much as 1.4 times longer in their residences than most adults, resulting in higher estimates of HC solvent exposures.

Infants

Since the physicochemical properties of the HC solvents indicate that they would be taken up by fatty tissue, the scenario of prenatal exposure, and hence risk to infants nursing from mothers exposed to HC solvents via inhalation, is reasonable. However, no data on HC solvents nor modeling (as was the case for PCE) are available for this scenario.

Summary

Although adult risk does not translate directly to infants, children, and the elderly, in scenarios where unacceptable risk levels have been determined for adults, there should be concern for similarly exposed (or dosed) sub-populations.

5.3.7 Environmental Risk—Summary and Conclusions

Risk Characterization—Hazard to Aquatic Organisms

The hazard of the HC solvents was assessed using limited toxicity data and structure activity relationships (SAR). Measured acute toxicity values ranged as low as 500 ppb for Stoddard solvent. SAR was used to estimate toxicity values for the individual components of the HC solvents (i.e., C9 to C12 linear paraffins and cyclic paraffins). Since the solvents are very similar chemically and contain approximately equal amounts of linear and cyclic paraffins, they were given the same hazard estimates. The estimated chronic toxicity values for both daphnid and algae are in the range of 80 ppb to 2 ppb which constitutes a high concern for chronic effects. The measured toxicity data for Stoddard solvent are consistent with the SAR predictions (WHO, 1996).

Risk Conclusions

The projected releases of HC solvents to surface water are negligible, on the order of 1×10^{-7} to 1×10^{-8} kg/site/year (Chapter 4). Resulting surface water concentrations are not expected to exceed the aquatic organisms toxicity concern concentrations (CC) of 0.001 mg/L for HC solvents (see Chapter 3 and Appendix B). Thus, there is a low risk of toxicity to aquatic species. Health risks to terrestrial animals were not evaluated.

Uncertainties

The risk conclusions are based on readily available toxicity and exposure data and on models, assumptions and professional judgements about toxicity and exposure information. These give rise to many uncertainties and assumptions and influence to a great extent how close the assessment of risk comes to realistic representation. Some central factors and uncertainties concerning environmental risk conclusions are listed below. Many of these are discussed in more detail in Chapter 4, and Appendices B and E.

- There was no assessment of risks to terrestrial species in this CTSA.

- The hazard assessment for aquatic species is not as certain as that for PCE since the HC solvents are chemical mixtures with uncertainty as to their exact composition, and to the extent that their chemical composition is uncertain, there is uncertainty in the SAR analysis.

- There are uncertainties as to the actual surface water levels, since estimated levels are based on estimated wastewater releases from drycleaning establishments, and an assumption that most establishments send effluent wastewaters to a POTW with subsequent further HC solvent removal.

Other Environmental Effects

None of the CTSA HC solvents have stratospheric ozone-depletion potential, but are volatile organic chemicals (VOCs) and are expected to contribute to lower-level photochemical smog levels. They also have global warming potential.

5.4 MACHINE WETCLEANING PROCESS

Two cleaning formulations were assessed for the machine wetcleaning processes. Water constitutes the majority of each formulation, and weight percentages of the chemical components range from 1% to 10%. Wetcleaning detergent formulations are complex mixtures typically containing water and a variety of different chemicals. Most formulations are trade secrets, and the concentrations of the individual chemicals are unknown to all but the manufacturer. In this CTSA, exposure estimates were based on two example detergent formulations (see Exhibit 2-7). Detergent #1 contains 10 constituents (plus water) and Detergent #2 contains 12 constituents (plus water). Seven constituents are common to both formulations.

5.4.1 Human Health

Very few toxicity data were available in the open literature on the chemical constituents of the two formulations. Some toxicity information, however, was found in reports of the Cosmetic, Toiletry and Fragrance Association (CTFA) (see Chapter 3 and Appendix C). These data do not indicate a potential toxicity for major systemic health effects from the chemicals as low percentage components in an aqueous solution. When hazard data were available, they were generally lacking on key health effects (such as cancer, developmental toxicity, etc.).

5.4.2 Human Health Risks

Risk—General

No oral RfD, inhalation RfC, cancer unit risk, or slope factor has been established to date for any of the sample wetcleaning chemicals reviewed for this CTSA. Unlike for PCE or the HC solvents, toxicity comparison values were not generated for these chemicals.

The example detergents are mixtures. Under ideal circumstances, toxicity information would be available for the mixture or formulation as a whole. More typically, information is available on some or all of the ingredients (components). Often, certain components are exchangeable, with selection based on their function in the process.

Routes of Exposure

Most detergent ingredients, and especially surfactants, are not likely to exist as vapors, mists, or dusts, and inhalation exposure is thus unlikely. Oral exposure to the general population is possible based on potential releases of detergent components to groundwater/surface water resulting in contaminated drinking water.

Since the formulations are expected to be aqueous liquids, the dermal route is the expected route of exposure. Little information is available concerning absorption of the components of the wetcleaning detergent formulations. No data are presented here for dermal absorption rates for the various detergent components.

5.4.3 Occupational Risks—Wetcleaning Workers

Risks from Inhalation and Dermal Exposure

Workers are expected to be the most highly exposed population to machine wetcleaning (MWC) detergent formulations. Dermal exposures are expected, but currently there are no data on actual worker dermal exposures. Inhalation exposure of workers is not expected because of the low volatilities of the component chemicals and because they are in aqueous solution. Dermal exposures to MWC formulations can be modeled, and these models are discussed in Chapter 4, and maximum modeled exposures listed in Exhibit 5-9, along with limited toxicity information. Workers can be exposed to diluted formulation or to full-strength. Maximum modeled exposures assume exposure to full strength formulation.

Operators are the primary workers expected to perform activities which result in dermal exposures to liquid MWC formulations, and these activities are shop- and equipment- dependent. Some of these activities occur at least once per day (routine) and others occur on a less frequent basis (non-routine). Routine activities include but are not limited to transferring wet articles from the washer to the dryer; and non-routine activities include but are not limited to connecting the formulation container to the dispensing pump line. Non-routine activities would more likely expose workers to full-strength formulations.

Risk Conclusions—Occupational Exposures

No quantitative estimate of health risks to workers is possible due to lack of sufficient hazard data. A complete qualitative assessment of risk also requires more extensive hazard data. An illustration of how the available information can be used, however, to indicate whether there can be irritation to workers from dermal exposure to wet process formulations is shown in Exhibit 5-9 using chemicals in the example detergent formulations. Although water is the major constituent of these formulations and the chemical constituents are expected to be found as 1–10% of the mixtures, some studies have suggested some irritant effects at such low concentrations. Sensitization and allergy, however, do not tend to be indicated (Appendix C).

Exhibit 5-9. Summary of Occupational Risk to Example Detergent Constituents via Dermal Exposure

Example Detergent Constituent (amount in formulation)	Example Detergent (taken from Ex. 2-7)	Max. Expected Dermal Exposure[a] (mg/day)	Observed Hazards Following Dermal Exposure in Humans[b]	Qualitative Comparison[c]
Example Surfactants				
Cellulose gum (5%)	1	195	100% soln = no irritation	L
Cocamidopropyl betaine (4.28%)	2	170	3% soln = maximum acceptable cosmetic use	P
Ethoxylated sorbitan monodecanoate (7.5%)	1	290	No irritation observed	L
Lauramide DEA (4.28%)	2	170	≥0.8% soln = mild irritation	L
Sodium laureth sulfate (4.28%)	2	170	≥ 0.5% soln = irritation	P
Sodium lauryl isethionate (3.75%, 2.14%)	1, 2	150, 83	Not enough information	—
Example Surfactant Aids				
Acetic acid (5%)	1	195	5% = vinegar	L
Citric acid (2.5%)	1	98	Not enough information	—
Sodium carbonate (10%)	2	390	50% soln = irritation to abraded skin	L

[a] Level reported in either Exhibit E-13 or E-14 for dermal contact with full-strength detergent formulation.
[b] Taken from Appendix C.
[c] L = low concern; P = potential concern.

Uncertainties

There is a high level of uncertainty as to the health risks to workers from using MWC formulations due to lack of toxicity data for most of the potential chemical constituents of the formulations.

5.4.4 General Population Risks

Dermal exposure of the general population to the component chemicals from wearing newly machine wetcleaned clothing is expected to be negligible. Potential oral exposures to MWC formulations that may be present in drinking water are also expected to be negligible, given the expected levels of less than 1 ppm in surface water for these chemicals (Chapter 4).

5.4.5 Environmental Risk—Summary and Conclusions

Risk Characterization—Hazard to Aquatic Organisms

Acute and chronic toxicity of the chemical constituents to aquatic organisms were estimated using SAR methodology. Almost all of the chemicals in the CTSA example formulation were given a "medium" hazard ranking, and none were considered "high" hazard (see Chapter 3).

All wastes from machine wetcleaning are released to water. The affected population thus is in the aquatic environment. Since these chemicals could be released from many drycleaning sites, site-specific data are not available. Generic assumptions were used to estimate surface water concentrations (USEPA, 1995), and streamflow values for streamflow values for (POTWs). This provides a conservative estimate of surface water concentrations and is appropriate for use when the specific sites are unknown (USEPA, 1995). (See Appendix E for more information.)

Environmental Risk Conclusions

Surface water concentrations were estimated for constituents of the two example wetcleaning formulations. Estimated surface water concentrations for Sample Detergent #1 formulation ranged from 0.04 t0 0.13 ppm. The concern concentrations for aquatic species were not exceeded by any of the chemical constituents. Estimated surface water concentrations for Detergent Sample #2 formulation ranged from 0.04 to 0.43 ppm. The concern concentrations (see Exhibit 3-2) of 0.06 ppm for lauric acid diethanolamide and 0.2 ppm for sodium lauryl isethionate were the only ones exceeded, indicating a hazard for aquatic species from these example constituents.

Uncertainties

There are uncertainties connected with using the structure-activity relationship (SAR) methodology for calculating the concern concentration. However, the combination of confirmation through cross-checking the literature which rests on the available database as well as the general history of usage of this technique lessens the uncertainty.

There are uncertainties as to actual surface water levels, since estimated levels are based on estimated releases of wetcleaning formulations from wetcleaning facilities, and an assumption that most establishments send effluent wastewaters to a POTW with subsequent further removal.

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